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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/117,921	03/04/1999	PIERRE BROUN	PM255164	8452

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EXAMINER

MCELWAIN, ELIZABETH F

ART UNIT PAPER NUMBER

1638

DATE MAILED: 04/08/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/117,921

Applicant(s)

BROUN ET AL.

Examiner

Elizabeth F. McElwain

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

The amendment filed January 21, 2003 has been entered.

Claims 1, 7-11 and 14-16 have been cancelled.

Claims 35-41 have been newly submitted.

Claims 35-41 are pending and are examined on the merits.

5 The text of those sections of Title 35, U.S. Code not included in this action can be found
in a prior Office action.

The rejections of claims 7-9, 11, 14 and 15 under 35 U.S.C. 112, second paragraph are
withdrawn in view of the cancellation of the claims.

10

Claims 39-41 are rejected under 35 U.S.C. 112, first paragraph, as containing subject
matter which was not described in the specification in such a way as to reasonably convey to one
skilled in the relevant art that the inventor(s), at the time the application was filed, had
possession of the claimed invention, as stated in the last office action for claims 8, 11 and 15-16.

15 Applicants' arguments filed January 21, 2003 have been fully considered but they are not
persuasive.

Applicants assert that the specification adequately describes the claimed invention in the
disclosure of a method of altering desaturase activity through the expression of catalytically
inactive forms of desaturases, and dominant negative mutants are just one embodiment of this
20 invention.

The Examiner maintains the rejection for claims 39-41, because these claims are not limited to use of nucleic acids encoding catalytically inactive mutant desaturases. These claims are broadly drawn to use of nucleic acids encoding any dominant negative mutant, wherein dominant negative mutants are not adequately described, as stated in the last office action.

5

Claims 35-41 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, as stated for claims 8, 9, 11 and 14-16 in the last office action.

10 Applicants' arguments filed January 21, 2003 have been fully considered but they are not persuasive.

Applicants argue that applicants teach general methods of producing transgenic plants comprising genes which alter fatty acid synthesis. Applicants also assert that the specification also teaches methods of altering desaturase activity through expression of catalytically inactive forms of desaturases, and that altering fatty acid content in plants does not have inherent unpredictability, pointing to pages 34-36 of the specification. Applicants further state that compliance with enablement does not require an example and that one of skill in the art would be able to practice the claimed invention.

15 The Examiner maintains the rejection given that the specification at pages 34-36 describes modification of fatty acid content by overexpressing genes encoding proteins having fatty acid desaturase activity and for use of antisense desaturase gene sequences. However, there

is no support provided for the effect of expression in a plant of a mutant desaturase that is catalytically inactive. It remains unclear and untested that the expression of a catalytically inactive desaturase in a plant will decrease fatty acid desaturase activity in the seed and alter the amount of unsaturated fatty acid in the seed. Given that the endogenous fatty acid desaturases will still be present in the plant, the effect, if any, of the mutant transgene is uncertain. The Examiner maintains that the effect of expression in a plant of a mutant desaturase that is catalytically inactive is highly unpredictable. Therefore, given said unpredictability; the lack of working examples; the absence of guidance in the specification, the breadth of the claims which encompass any mutant desaturase genes that are catalytically inactive; and given the state of the prior art, which does not teach the effect of the expression of a mutant desaturase on the transgenic plant; it would require undue experimentation by one skilled in the art to make and/or use the claimed invention.

See *Ex parte Formal* 230 USPQ 546 (PTO Bd. App. Int. 1986), where it was taught "the disclosure of a patent application must enable the practice of the invention claimed without undue experimentation", wherein factors involved in the determination of undue experimentation were deemed to include "the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art and the breadth of the claims". Also see *Ex parte Hitzeman*, 9 USPQ 2d 1821, 1823 (PTO Bd. App. Int. 1988), where the unpredictable physiological art was deemed to require more than one embodiment for the enablement of broad claims.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

It is suggested that Applicant begin using the new format for entry of amendments, as set forth at <http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/revamdtprac.htm>.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (703) 308-1794. The examiner can normally be reached on Monday through Friday from 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone number for this Group is (703) 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Any inquiry of a general nature or relating to the status of this application should be directed to the CUSTOMER SERVICE TECH CENTER 1600, whose telephone number is (703) 308-0198, or to the Group receptionist whose telephone number is (703) 308-0196.

Serial No. 09/117,921
Art Unit 1638

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Elizabeth F. McElwain, Ph.D.
April 3, 2003


ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1600